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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/144,886	08/31/98	MARKS	J 2307E-826US

HM22/1214  
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EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

12/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/144,886

Applicant(s)

Marks et al

Examiner

LI L

Group Art Unit

1645

☒ Responsive to communication(s) filed on Sep 18, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-43 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-43 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1645

### DETAILED ACTION

1. Applicant's amendment filed on Sep 18, 2000 (Paper Number 13) has been received and entered. Claims 44-77 have been canceled, claims 1 and 24 have been amended, consequently claims 1-43 are pending in the instant application.

2. The rejection of claims 6-10, 17-43 under 35 U.S.C. 112, second paragraph, as being indefinite for using the terms "variable heavy complementarily determining regions (CDRs) listed in Table 4", "variable light complementarily determining regions (CDRs) listed in Table 4", "framework region listed in Table 4", and "the antibody of claim 1" is maintained.

In response to applicant's argument that Table 4 expressly provides complete amino acid sequence information for frameworks 1-3 and CDR 1-3 and Table 4 uses dashes "-" to identify amino acids common to ~~the~~ all the listed sequences, it is noted that claims do not recite any specific SEQ ID NO for the claimed antibody nor any specific SEQ ID NO <sup>for the</sup> frameworks or CDRs. Furthermore, those frameworks and CDR regions in ~~the~~ Table 4 are not clearly defined by specific sequence or by the specific property and characteristic. Without clearly defined amino acid sequence for the claimed antibody, one <sup>of</sup> ordinary skill ~~ed~~ in the art cannot determine the metes and the bounds of the claims.

In response to applicant's argument that it is well accepted that antibodies can and are described structurally and/or by the epitope to which they bind, it is noted that the recitation of "the antibody of claim 1" in claim 17 does not indicate any property or characteristics of the antibody of claim 1. There are two different antibodies in claim 1, an isolated antibody and an

Art Unit: 1645

antibody expressed by a clone. Each of the antibodies can have a framework region listed in Table 4 no matter if it binds to an epitope or not.

3. The rejection of claims 1-11, 13-14, 17-30, 32-33, 36-43 under 35 U.S.C. 102(b) as being anticipated by Atassi et al (J Protein Chem 15 (7): 691-699, 1996 in Form 1449) is maintained.

In response the applicant's argument that Atassi et al only disclosed the creation of native antibody, the art teaches that any native antibody is formed from two single chains, a heavy chain and light chain. Each of the single chains of Atassi's antibody meets the limitations of the claims, e.g., it specifically binds to an epitope of botulinum neurotoxin type A (BoNT/A) and it can be used in passive immunity/neutralizing against the toxin poisoning because they both contain variable regions which can specifically bind to an epitope.

4. The rejection of claims 1-43 under 35 U.S.C. 102(a) as being anticipated by Amersdorfer et al (Infect Immun 65 (9), 3743-3752, 1997) is maintained.

In response the applicant's argument that James Mark and Peter Amersdorfer are both listed as authors in the reference, it is noted that the inventive entities are different between the cited reference and the instant application. The cited reference has six authors who are not inventors of the instant application. The rejection under 102(a) is proper and therefore is maintained.

5. The rejection of claims 1-43 under 35 U.S.C. 103(a) as being unpatentable over Atassi et al (J Protein Chem 15 (7): 691-699, 1996 in Form 1449) and Emanuel et al (J Immunol Meth 193: 189-197, 1996) is maintained.

Art Unit: 1645

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As discussed above, each of the single chains of Atassi's antibody meets the limitations of the claimed single chain. Atassi et al do not teach a particular single chain Fv (scFv) antibody or a (scFv)<sub>2</sub> antibody. However, Emanuel et al teach a recombinant single chain antibody anti-BoNT. The antibodies were generated by immunizing mice with botulinum toxoid types A, B, C, ~~D~~<sup>E</sup>, and ~~D~~ (2.2 Mice immunization protocol for recombinant antibodies) and the antibodies can specifically bind to an epitope of botulinum toxoid type A (Table 1, cell lines Bot01, BotFab1, BotFab 7, etc.). Therefore, the combination of Emanuel et al and Atassi et al <sup>make obvious</sup> ~~will arrive to the level of~~ the claimed invention.

### Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1645

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Status of Claims*

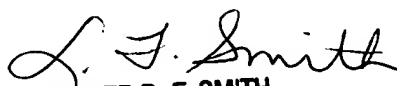
7. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee  
December 8, 2000

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600